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N-GC

UNIVERSITY OF WASHINGTON

0144 '98 JAN -7 A11 :47 Consult to DSI mgm

1997 December 24

CENTER FOR DRUG EVALUATION AND RESEARCH

DEC 29 1997

RECEIVED HFD-120

Paul Leber, MD
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research
Food and Drug Administration
Rockville, MD 20857

Re: IND 52,523 for magnesium sulfate and diazepam injection after cardiac arrest

Dear Dr. Leber:

In your letter dated 1997 October 17, you indicated a need to receive copies of information concerning public disclosures (see item number 1).

Enclosed please find two copies of materials related to community consultation carried out in preparation for this study and a reply from the Human Subjects Review Committee at the University of Washington. As you can see from the correspondence dated 1997 December 19, the Committee has reviewed these materials and has indicated that we have met all the requirements for implementation of waiver of consent for this study. The Committee also suggested that we send these materials to you (see item number 3).

We are hoping to initiate the study sometime in 1998 January. If you have any questions about these materials or the study, please contact me as soon as possible. Best wishes for the holidays.

Sincerely,

W.T. Longstreth, Jr, MD
Department of Neurology
Box 359775
Harborview Medical Center
325 Ninth Avenue
Seattle, WA 98104-2499

voice: (206) 731-3251
facsimile: (206) 731-8787
electronic mail: wl@u.washington.edu

95-5-0158

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University of Washington Correspondence
INTERDEPARTMENTAL
Office of Research
Grant and Contract Services
Human Subjects Division Box 355752

December 19, 1997

W. T. Longstreth, Jr., M.D.
Department of Neurology
Box 359775

Dear Dr. Longstreth:

Re: Human Subjects Review Committee Application No. 27-0313-A entitled "Brain Cardiopulmonary Resuscitation: Magnesium, Diazepam, Both, or Neither"

Thank you for your letter of November 25, 1997, and submission of community consultation and public notification results regarding the above-referenced application. Human Subjects Review Committee A read and discussed these materials at a Committee meeting on December 10, 1997.

The Committee has determined that you have met all of the requirements for implementation of waiver of consent for this study. We approve the use of waiver of consent for this study and grant you authorization to begin the study.

Please also note our specific comments, below.

Additional information

1. Thank you for the report on the comments from the telephone questionnaire, the PSA/advertisement, the meeting with cardiac arrest survivors, and the mailing to cardiologists in Seattle and emergency room directors and nursing directors of intensive care units for Seattle hospitals. The Committee felt that the breadth and detail of the community consultations regarding the waiving of consent for this particular study provided sufficient input from the community. We note that all of the responses were positive. The telephone survey was particularly interesting in that it allowed for a broad range of people to express very specific opinions about the research. We note that the majority of those called (>70%) did support the study, would want to participate, would want a family member to participate, and felt that waiver of consent could be justified under these circumstances.

   It is interesting that the main concern that came up several times was not the issue of the need to waive consent, but rather a design issue - the need for placebos in clinical trials. It appears that you have been able to explain to those who inquired why placebos are necessary. We feel that you have responded appropriately to the comments elicited by the community consultations and we note that no changes are needed in the study design.

2. Please keep us informed as to your progress in obtaining approval from the other hospital IRBs in the area who may be receiving patients who have been enrolled in your study. We hope that our approval of your study and our authorization for you to proceed will help to facilitate the approval process at the other institutions.

3. In terms of your questions regarding the FDA letter of October 17, 1997, our interpretation is that the FDA would like to receive from you the same materials that you sent the Committee regarding the nature and results of the community consultations and public disclosure. As stated in their letter, they need to have on file "copies of the information that was disclosed, identified by the IND number." In addition, the FDA also needs, on an ongoing basis, any other public comments besides those which you have already received, in order to monitor any public opposition to the project.

We wish to thank you for your continued patience and cooperation in working with us toward obtaining approval of this study and approval of waiver of consent. The Committee realizes that it has been a difficult and somewhat arduous process. Undoubtedly, future applications requesting use of waiver of consent in emergency circumstances will become easier to review, approve, and execute as a result of your efforts at this time.

If you have questions concerning this letter, please contact Dr. Erica Jonlin, Human Subjects Review Coordinator, at 543-4798. We look forward to receiving the report on the results of the pilot study, as well as the new application for the randomized trial.

Sincerely,

Zane A. Brown, M.D., Chair
Human Subjects Review Committee A

ZAB:ej

University of Washington Correspondence

INTERDEPARTMENTAL

Date 1997 November 25

To: Zane A. Brown, MD
Chair, Human Subjects Review Committee A
Human Subjects Division
Grant and Contract Services
Box 355752

From: W.T. Longstreth, Jr, MD
Department of Neurology
Harborview Medical Center
Box 359775

RE: Community Consultation for
Human Subjects Review Committee Application No. 27-0313-A
"Brain Cardiopulmonary Resuscitation"

Although I have not received any calls about the Public Service Announcement for about three weeks, I was called today by a 90 year old man.

He indicated that his associates at his nursing home and he had discussed the announcement. The main question related to people who have gone through the process to make themselves a no code. Would they be forced to be resuscitated and enrolled in the study? I explained that only those patients who the paramedics resuscitated would be eligible for the study. If a patient did not want to be resuscitated, specific things needed to be done to assure that neither the paramedics nor anyone else would attempted cardiopulmonary resuscitation. He was familiar with the State laws relating to these issues.

Otherwise, he said that everyone was supportive of the study being done. The waiver of consent was not an issue.

University of Washington Correspondence

Human Subjects Division

INTERDEPARTMENTAL

NOV 2 5 1997

UW

Date 1997 November 24

To: Zane A. Brown, MD
Chair, Human Subjects Review Committee A
Human Subjects Division
Grant and Contract Services
Box 355752

From: W.T. Longstreth, Jr, MD
Department of Neurology
Harborview Medical Center
Box 359775

RE: Community Consultation for
Human Subjects Review Committee Application No. 27-0313-A
"Brain Cardiopulmonary Resuscitation"

This correspondence concerns community consultation, the final step necessary to secure approval to use a waiver of consent in this study. Herein, my co-investigators and I will review the results of the community consultation that we had outlined in our original proposal. Before turning to the result, we will briefly review the study design. The study is a population-based, double-blind, placebo-controlled clinical trial of magnesium sulfate, diazepam, both, or neither given intravenously by Seattle Fire Department paramedics to patients whom they have resuscitated from cardiac arrest. These two injections are the only study interventions. Otherwise, paramedics will treat all patients in the standard fashion. All of the information on outcomes will come from data collected routinely by Medic One personnel as part of the organization's ongoing quality assurance activities. The study hypothesis is that one or both of these agents will increase the chances of patients' regaining consciousness - awakening - after their arrest. The study is summarized in the Figure contained in Appendix 1.

The study is not possible without waiver of consent. As you know, we have worked with the Human Subjects Review Committee at the University of Washington and the Food and Drug Administration to obtain approval to use the waiver. One of the requirements entails community consultation about the study before it is initiated. We proposed four approaches for community consultation. The results of each will be reviewed.

The first approach involved random digit dialing to identify 35 residents of Seattle over age 40, the population that will contain most of the subjects of the study. After an eligible person in the household was identified, the interviewer explained the purpose of the call, described the design of the study, and

solicited opinions. The telephone script used was approved by the Human Subjects Review Committee and is contained in Appendix 2A. A professional telephone interviewer, Cathy Papp, performed the random digit dialing on 1997 August 17 through August 21 and August 25 through 27. She was provided 500 telephone numbers with Seattle prefixes and was able to interview 35 eligible Seattle residents. The interviewer's work sheets are contained in Appendix 2B, and 35 interview sheets are in Appendix 2C. Of the 35 people, 5 (14.3% with 95% confidence interval by the binomial distribution 4.8 to 30.3) did not support the study, would not want to participate, and would not want a family member to participate. One person did not support the study, would not want to participate, but was unsure about having a family member participate. One person was uncertain about all three questions but declined the offer to discuss the study with one of the investigators. In fact, all 35 people were offered the opportunity to discuss the study further with an investigator, but all declined. One person did not support the study but would want to participate and would want a family member to participate. Finally, one person supported the study and would want a family member to participate but did not want to participate himself, explaining that he was over 80 years old and had a pacemaker. All of the remaining 26 people (74.3 with 95% confidence interval 56.7 to 87.5) supported the study, would want to participate, and would want a family member to participate. Based on comments written on the interview sheets and discussion with the interviewer, the main concern expressed by people concerned the use of a placebo. No one directly expressed concern over the issue of waiver of consent.

The second approach involved a meeting of the study personnel with a group of survivors from out-of-hospital cardiac arrest. Thirteen Seattle residents who were survivors of out-of-hospital cardiac arrest were contacted. Six indicated a willingness to attend a meeting and five came, one with his wife. At this meting on 1997 August 16, the study personnel explained the study using the same sort of information as in the telephone script. The other seven who were unable to attend were interviewed over the telephone using the script used for the random digit dialing. Summaries of all these contacts are contained in Appendix 3. All six attendees of the meeting supported the study, would want to participate and would want a family member to participate. Similar results were obtained from the seven survivors who were interviewed over the telephone except that one who would not want to be resuscitated again. This person supported the study and would want a family member to participate. Interestingly, much of the time at the meeting was spent discussing study design and in particular the need for placebos. Those attending the meeting seemed satisfied with the explanations provided, and all supported the study. No one directly expressed concern over the issue of waiver of consent.

The third approach was to place a public service announcement describing the study in the Seattle Times. We held off on this aspect of community consultation until we had secured approval for the study from the Food and Drug Administration. A copy of the announcement is included in Appendix 4. A

telephone number for the study was provided for those having any further questions. I was also contacted by KIRO News Radio and was interviewed about the study. This interview was aired soon after the announcement was published in the Seattle Times on 1997 October 30. I received six calls about the study. One person worked for a Head Injury Hotline and was interested in more details about the study and the agents being studied. The other five people were Seattle residents who wanted to discuss the study. Again, the main concern was with the use of placebos. We discussed issues about study design and about the benefits of using placebos. Everyone seemed satisfied to varying degrees with my explanations. All were supportive of the study by the end of our conversations. None of the people directly expressed concern over the issue of waiver of consent.

The fourth and final approach entailed a mailing to 132 cardiologists in Seattle and to 7 emergency room directors and 19 nursing directors of intensive care units for Seattle hospitals. The letter explained the study. The letter was approved by the Human Subjects Review Committee and a copy of it is contained in Appendix 5. The recipients of these letters were asked to contact one of the investigators if they have any questions or concerns about the study. I received a single call from a physician at Swedish Medical Center who indicated that they were eager to participate in the study.

To summarize, the main concern raised in this community consultation was the need for placebos in clinical trials. When an investigator was given an opportunity to explain why placebos were needed, such as at the meeting with survivors of cardiac arrest and in conversations with those who called after the public service announcement, everyone was supportive of the study. In none of the community consultations was the issue of waiver of consent the main concern. The community consultation has not suggested that we should change the current study design.

Finally, we would appreciate your advice about what communications are necessary with the Food and Drug Administration based on their last letter dated 1997 October 17 and item 1, "Obligations Associated With 21 CFR 50.24". For your convenience, we have included this letter in Appendix 6. If you have any questions concerning these materials, please contact me. Thank you for your help with this project.

Appendix 1.

Figure summarizing the Brain-Cardiopulmonary Resuscitation Trail

Clinical Trial of Magnesium, Diazepam, or Both After Cardiac Arrest

Study Subjects

300 patients 18 years or older resuscitated from cardiac arrest by Seattle Medic One paramedics over two years

Study interventions begun as soon as possible after return of pulse and blood pressure

Patients must not have awakened prior to the study interventions and must have endotracheal intubation

Number of Patients Randomized to Each Group

	diazepam-active	diazepam-placebo	total
magnesium-active	75	75	150
magnesium-placebo	75	75	150
total	150	150	300

Study Interventions

Injection #1

4 ml syringe with 2 gm magnesium sulfate
or an identical appearing
4 ml syringe with normal saline

Injection #2

2 ml syringe with 10 mg diazepam
or an identical appearing
2 ml syringe with normal saline

Study Outcomes

Primary — awakening (yes, no)

Secondary — time to awakening (days)
time to death (days)
neurologic recovery (awake with independence, awake without independence, not awake)

best neurologic recovery by hospital discharge
best neurologic recovery by 3 months after arrest
neurologic recovery at 3 months after arrest

Appendix 2.

Community Consultation: Random Digit Dialing

A. Telephone script approved by
University of Washington Human Subjects Review Committee

TELEPHONE INTERVIEW
FOR
BRAIN CARDIOPULMONARY RESUSCITATION (BCPR) STUDY

1. **Hello. My name is _____ , and I'm calling on behalf of University of Washington researchers who are planning a study involving people who have had a cardiac arrest. I am not calling for a donation. I am interested in hearing your opinions about the proposed study. The University of Washington and the U.S. Food and Drug Administration have asked us to collect opinions before the study can begin.**

   I would like to tell you about the study and ask you two brief questions, if I may. This should take less than 5 minutes of your time.

(IF REFUSAL, GO TO EXIT 1.)

EXIT 1: *Thank you for your time. Goodbye.*

2. **I need to speak with someone who is 40 years old or older. Are you at least 40 years old?**

   (IF YES, GO TO 3; OTHERWISE CONTINUE.)

   May I please speak with someone who is 40 or older?

   (IF NEW RESPONDENT AVAILABLE, GO TO 1 AND THEN 3; OTHERWISE CONTINUE.)

   When would be a good time to call back to speak with them?

(RECORD APPOINTMENT ON CONTACT SHEET; USE EXIT 2.)

EXIT 2: *Thank you. I'll call back at that time.*

3. **The study is designed to find a treatment that can reduce the brain damage that can follow a heart or cardiac arrest. During a cardiac arrest, the heart stops pumping blood, including to the brain. Brain damage may result. Paramedics treat patients for a cardiac arrest and then bring the patients to a hospital for admission. Unfortunately, about a half of these patients do not survive, often because of severe brain damage that has occurred during the cardiac arrest.**

   Researchers at the University of Washington want to do a research study in which Seattle paramedics would give, as soon as possible after the cardiac arrest, drugs that may reduce brain damage if given early enough. To see if this new treatment helps, the paramedics will give some patients an inactive substance, called a placebo. All patients will in addition receive the usual treatments that cardiac arrest patients receive. No one will go without treatment. The researchers will look at how well the patients who have received the additional medications do compared to the patients who receive the placebo. They will study both the benefits as well as the risks of the new treatment. The study drugs are commonly used for other conditions, but not for cardiac arrest. These drugs are not expected to cause any serious risks to the patients.

   Usually, before a patient is involved in a research study, the researchers discuss the study with the patient or their family. If the patient or their family agrees, the

patient is then enrolled in the study. This process of discussing the study with the patient and getting their permission to enroll them in the study is called "informed consent." However, in the cardiac arrest study I am telling you about, it will not be possible for the researchers or the paramedics to get informed consent from the patients because the patients will all be unconscious. The drugs have to be given so quickly that it will also not be possible for the researchers or paramedics to find a family member and get informed consent from them.

4. My question for you is: Would you support such a study being done in your community, specifically, a study in which patients and their families do not have a chance to give their consent to be in the study?

(RECORD RESPONSE ON CONTACT SHEET.)

5. If you had a cardiac arrest and were treated by Seattle paramedics, would you want to be enrolled into this type of study?

(RECORD RESPONSE ON CONTACT SHEET.)

6. If a family member of yours had a cardiac arrest and were treated by Seattle paramedics, would you want him or her to be enrolled into this type of study?

(RECORD RESPONSE ON CONTACT SHEET.)

7. I appreciate your sharing your opinions with me. Do you have any other thoughts or comments about this proposed study?

(RECORD RESPONSE ON CONTACT SHEET.)

8. Thank you again for your time and help with this study.

SUGGESTED RESPONSES TO COMMONLY ASKED QUESTIONS

(IF RESPONDENT QUESTIONS YOUR AFFILIATION WITH THE UNIVERSITY OF WASHINGTON:)

You can verify my association with the University of Washington by calling 731-3000 and asking for extension number 3251. This is the office telephone number for the principal investigator, Dr. Longstreth, at Harborview Medical Center.

(IF RESPONDENT ASKS WHY HE OR SHE WAS CALLED:)

People often ask why they were contacted. We simply pick Seattle telephone numbers at random, call them, and ask if people would be willing to help with the study. The survey about this study is required by federal regulations because it involves studying patients in an emergency situation before consent can be obtained.

(IF RESPONDENT ASKS ABOUT THE MEDICATIONS TO BE USED IN THE STUDY:)

The study will evaluate two medications. One is magnesium sulfate and the other is diazepam or Valium. In experiments in animals, both of these medications seem to protect the brain from the sort of injury that can occur when the supply of blood flowing to the brain is temporarily interrupted, as occurs with a cardiac arrest. Magnesium is common used in patients found to be deficient in this mineral and for some of the complications that can occur late in pregnancy. Diazepam is a medication that can make people sleepy. It is commonly used for this purpose in patients both in and outside the hospital.

(IF RESPONDENT ASKS FOR MORE DETAILS REGARDING THE STUDY:)

For some questions, I may not be the best person to ask. If you would like, I can ask one of the investigators in this study, Dr. Longstreth, to call you and to try to answer your questions.

Appendix 2.

Community Consultation: Random Digit Dialing

B. Interviewer's work sheets

BCPR STUDY

DATE	TIME IN	TIME OUT	TOTAL HOURS
Aug. 17, 1997	5:30 PM	7:30 PM	2
Aug. 18, 1997	7:00 PM	9:00 PM	2
Aug. 19, 1997	6:00 PM	8:00 PM	2
Aug. 20, 1997	7:30 PM	8:30 PM	1
Aug. 21, 1997	7:00 PM	8:30 PM	1.5
Aug. 25, 1997	7:00 PM	8:30 PM	1.5
Aug. 26, 1997	6:00 PM	7:30 PM	1.5
Aug. 27, 1997	1:00 PM	2:00 PM	1
Aug. 27, 1997	3:00 PM	3:30 PM	1.5
Aug. 27, 1997	7:00 PM	8:00 PM	1
			14 hrs

Cathy R. Papp 318 Bedrock Dr. #1 Everett, WA 98203
(425)355-2332

All calls on Sprint during this time are for this study. None for the Menengioma Study.

Cathy Papp

Telephone	Contact	Eligible	Agreeable	Date
				8-17-97
248-9558	8 modem/fax			
782-0738	8- D/C			
525-9917	1	2		
324-4596	2			
991-0258	8- page			
433-1753	1	1	1	
783-7353	1	1	1	
544-3514	8 Business			
783-3893	2			
662-5647	8 2			
977-8510	8 pager			
217-3999	8 Business (machine)			
782-8802	8 Blocked			
323-4813	8 modem/fax			
282-4795	1	1	1	
728-8655	1	2		
286-8052	1	1	1-	
283-7453	8 BUSINESS (NO)			
443-8315	2			
233-2654	8 modem/fax			
223-8437	8 D/C			
467-5507	3			
723-2715	3			
443-2731	2	call back		
728-1090	8 D/C			
284-6043	1	2		
343-1698	8 D/C			
516-2356	8 UK			
782-1989	1	1	1	
654-7854	8 D/C			
233-6011	8 UK			
447-5057	8 BZ			
721-5203	8 Business			
991-2406	8 D/C			
997-0904	8 Business			
447-3936	2			
292-6561	8 Business			
362-4554	1	1	1	
469-5863	8 Pager			
283-5392	8 UK			
322-2485	8 D/C			
322-5372	8 modem/fax			
367-6145	1	2		

D/C = disconnected
UK = unknown
BZ = Business

Double page

Telephone	Contact	Eligible	Agreeable	Date
				8/17/97
248-9558	8-for/modem			
782-0738	8 D/C			
525-9917				
324-4596				
991-0258				
433-1753				
783-7353				
544-3514				
783-3893				
662-5647				
977-8510				
217-3999				
782-8802				
323-4813				
282-4795				
728-8655				
286-8052				
283-7453				
443-8315				
233-2654				
223-8437				
467-5507				
723-2715				
443-2731				
728-1090				
284-6043				
343-1698				
516-2356				
782-1989				
654-7854				
233-6011				
447-5057				
721-5203				
991-2406				
997-0904				
447-3936				
292-6561				
362-4554				
469-5863				
283-5392				
322-2485				
322-5372				
367-6145				

230-3463	8 PAGER			8/17/97
431-1724	1	2		
442-1579	8 Modem/fax			
544-7675	8 Business			
933-7098	2			
783-2339	8 D/C			
410-5554	8 D/C			
281-0390	8 Business			
682-4619	8 modem/fax			
217-6944	8 D/C			
525-8261	1	1	1	
522-3248	1	2		
993-7252	8 D/C			
991-3639	8 pager			
343-2904	2			
621-2509	8 D/C			
624-6742	2			
587-3791	2			
386-3659	2			8-17-97
440-8742	8 D/C			8-18
706-9050	3			
286-3237	8 Business			
764-3564	2			
324-2429	1	1	1	
448-3870	8 Business			
609-5133	8 Pager			
624-0765	3			
621-3664	8 D/C			
517-5473	1	2		
662-4299	8 D/C			
938-4809	3 Young			
524-2570	3 Young			
528-7594	8 D/C			
937-5356	1	2		
955-2777	8 Pager			
410-7244	8 D/C			
662-9765	3			
938-9955	3			
389-8444	3			
230-3816	3 Young			
217-3930	8 BUSINESS (NO)			
544-6534	8 Business			
935-9548	1	3	8/27	
328-4745	1	2		
442-7754	8 modem/fax			
243-7236	1	1	1	

7:30p

7pm

517-3498	8 Business			8-18-97
215-2667	8 BZ fax			
328-6727		3		
248-8659	8 D/C			
682-2415	8 D/C			
364-5211	1	1	1	
361-5891	8 D/C			
282-1412	8 Business			
322-3554	3			
977-8291	8 pager			
544-9827	8 Business			
440-2784	2			
361-6825	8 Business			
720-8333	1	1	2	
242-9060	8 BZ			
325-5674	8 D/C			
522-6155	2			
547-6346	3			
284-7179	2			
545-8582	1	2		
325-5026	1	2		
782-1684	1	2		
682-9849	2			
993-8917	8 D/C			
721-0165	8 D/C			
524-9505	3 1	1	1	
246-7677	8 modem/fax			
762-8054	1	1	1	
243-6431	8 Business			
298-6496	8 D/C			
547-6724	8 D/C			
343-5310	2			
236-2172	1	1	1	
367-9503	1	2		
587-3714	8 D/C			
608-9837	3 (YOUNG)			
236-9023	8 pager			
386-6478	2			
365-6264	1	3		
767-2105	8 D/C			
725-3740	3			
389-2730	8 BUSINESS [illegible]			
991-6382	8 pager			
575-7487	8 Business			
343-1790	8 D/C			
241-7043	8 D/C			

2nd call 8/27

129

609-9749	8 Pager				8/18/97
933-2889	8 D/C				
583-3509	8 Business				
506-6780	8 Business				
521-5258	8 modem/fax				
364-1478	1		1		
410-3599	8 D/C				
284-9739	2				
431-8349	2				
324-8545	8 modem/fax				
760-7336	8 D/C				
433-3406	2				
624-2463	2				
282-6588	1	3			
781-8490	8 D/C				
367-5006	1	2			
522-2322	1	1	1		8/18/97
363-8932	8 D/C				8/19
522-6530	1	1	1		
728-9507	2				
723-6642	1	1	1		
521-5552	8 UK				
443-0225	8 D/C				
213-3960	8 Business				
682-3511	8 modem/fax				
991-4914	8 PAGER				
232-0992	2				
583-4785	8 Business				
622-8345	8 D/C				
236-5578	8 PAGER				
517-3622	8 BUSINESS				
548-8568	8 BZ (FAST)				
469-3261	8 D/C				
216-2598	2				
763-2651	8 Business				
322-0999	8 D/C				
523-5213	8 BZ				
860-9354	2				
721-1341	8 D/C				
723-2216	8 Business				
720-8636	8 D/C				
298-6909	8 Business				
216-5453	2				
232-0618	1	3			
991-1069	8 D/C				
528-5837	3				8/19/97

2 hrs.

9pm
6p

328-8721	3			8/19/97
781-8738	8 D/C			
722-6559	1	1	1	
548-4168	2			
386-3609	2			
938-0669	8 fax			
443-8852	8 D/C			
784-6934	3			
361-0581	8 modem/fax			
528-7931	8 D/C			
995-1142	8 PAGER			
440-6896	8 BUSINESS			
340-7471	8 D/C			
215-0490	8 D/C			
789-4864	3			
721-0613	3			
622-3780	2			
608-8065	8 Business			
506-4486	8 Business			
516-7728	2			
242-3647	1	2		
789-2400	8 Business			
527-2599	3/1	2		2nd call 8/21
772-3001	1	2		
609-8775	8 Business			
361-0581	8 modem/fax			
789-9440	3/1	1	1	-2nd call 8/21
213-2146	2			
241-1326	2			
281-0810	2			
860-5945	8 Business			
767-8445	8 (FAST BZ)			
443-5890	8 D/C			
325-3059	3 - 1	1	1	
389-4008	2			
243-1011	2			
994-8653	8 PAGER			
389-7730	8 BUSINESS			
772-6252	2			
246-6428	1	1	1	8/19 8/21
241-7782	8 BUSINESS			
447-3204	8 BUSINESS			
433-4257	8 D/C			
232-8380	1	1	1	2nd call 8/25
410-7792	8 D/C			
216-3987	8 BUSINESS			8/19/97

2nd 8/27

8/19

7:30P

Recalled 7/21

243-2912	3 1	1	1	8-20-97
784-2162	8 Business			
365-1395	3			
782-3214	1	1	1	
282-2729	1	3		
515-1673	8 Business			
521-3657	8 BZ (FAST)			
772-0122	2			
236-3337	8 Business			
723-5162	8 D/C			
386-9103	2			
215-6546	8 (BZ FAST)			
632-7541	1	2		
583-1820	8 D/C			
292-5903	8 D/C			
217-9165	8 D/C			
545-6876	8 Business			
993-0383	8 D/C			
726-8287	8 BZ			
522-8687	8 BZ			
236-3594	2			
364-7868	1	2		
328-2175	1	2		
223-5999	8 D/C			
284-2170	2			
994-0157	8 D/C Pager			
587-2957	8 Business			
760-0062	8 D/C			
439-6689	8 Business			
441-9898	8 D/C			
762-7472	8 D/C			
977-1710	PAGER			
284-4826	8 Business			
322-2823	8 modem / fax			
623-6661	1	1	1	
322-4604	8 D/C			
517-9820	8 BUSINESS			
340-5839	8 PAGER			
363-1107	2			
517-9009	8 Business			
389-9387	8 modem / fax			
781-2760	3			
706-5049	8 D/C			
524-6065	1	1	2	
725-9559	3			
860-3981	8 modem / fax			8/20/97

991-6270	8 D/C	(pager)		8/21/97
615-3356	8 Business			
364-4422	8 Business			
609-1656	8 PAGER			
363-0020	8 UK			
344-6434	8 BUSINESS			
504-5381	8 D/C			
763-6303	8 D/C			
723-6203	1	1	1	
516-4796	2			
328-6649	8 D/C			
325-7519	2			
270-6250	2			
292-6716	8 D/C			
625-6373	2			
706-3606	8 D/C			
706-7297	2			
329-9191	8 Business			
527-0926	2			
526-3580	8 D/C			
368-7251	2			
329-7500	2			
322-7277	2			
781-1414	2			
706-1367	8 D/C			
517-5225	2			
544-2245	8 BUSINESS			
285-2385	1	1	2	
937-5208	1	2		
955-2593	8 D/C (PAGER)			
224-1763	8 BUSINESS			
467-6304	2			
654-4272	2			
720-4484	2			
448-0897	8 BUSINESS			
625-1119	8 D/C			
633-2904	8 D/C			
325-5308	2			
410-6620	8 D/C			
213-1674	8 BUSINESS			
298-4041	2			
340-9492	8 BUSINESS			
230-0169	8 D/C			
728-2124	8 BUSINESS			
720-9170	8 D/C			
991-2306	2 PAGER			8/21/97

7 pm

344-5304	2			8-25-97
283-9698	3			
526-7700	8 Business D/C (unassigned #)			
722-4313	3			
662-1060	8 Business			
784-8425	2			
515-0893	8 (unassigned #)			
364-1905	8 D/C			
977-1850	8 PAGER			
517-1242	8 Business			
215-3222	8 B2 (FAST)			
782-3121	2			
610-9145	8 D/C PAGER			
995-7463	8 PAGER			
224-7617	8 modem/FAX			
232-6407	8 B2			
937-2178	1	1	1	
243-6874	8 B2			
248-9678	3			
654-6206	8 D/C			
662-2125	8 BUSINESS			
389-1977	8 UK			
467-9244	3			
991-7135	8 D/C PAGER			
933-2242	8 BUSINESS			
367-8357	8 BUSINESS			
216-5857	8 BUSINESS			
938-6734	1	2		
367-5002	1	2		
789-3902	8 modem/fax			
935-0078	8 D/C			
283-5635	8 D/C			
610-2117	8 PAGER			
344-1010	8 PAGER			
522-9994	8 D/C			
523-7330	1	2		
933-5548	8 Business			
368-1850	2			
283-0965	2			
587-9868	8 PAGER			
343-7848	8 D/C			
517-3438	8 unassigned #			
323-0013	8 D/C			
469-7692	8 PAGER			
995-3085	8 D/C PAGER			
583-9456	8 PAGER			8/25/97

10 Pager
7 D/C
8 Business

3 unassigned

17 possibles

516-6060	8 D/C				8-25-97
270-9613	8 BZ				
525-3896	8 D/C				
767-4990	1	2			
431-7814	1	2			
443-1006	2				
544-5871	2				
548-7686	8 Business				
654-7554	8 Business				
386-9615	2				
368-6661	8 BZ				
284-5553	8 D/C				
784-8896	1	1	1		
464-3853	8 Business				
525-0157	8 modem / fax				
764-1898	1	1	1		
760-6018	8 D/C				
364-4071	8 BZ				
281-2579	3				
610-0449	8 PAGER				
545-0596	8 D/C				
340-1621	8 D/C				
772-6441	2				
768-7962	8 D/C				8/25
216-6321	2				8/26
361-6705	2				
517-1219	8 Business				
575-3856	8 modem/fax				
575-0831	2				
223-8398	8 D/C				
441-5837	1	2			
955-6942	8 PAGER				
285-4566	2				
935-1712	2				
517-1717	8 Business				
615-1560	8 D/C				
523-6833	1	1	1		
526-3438	8 D/C				
525-8744	2				
230-7862	8 [illegible]				
544-6875	2 not assigned [illegible]				
328-1086	2				
723-5004	3				
232-1545	2				
521-9608	8 Business				
323-1406	8 D/C				8/26

1 1/2

2nd call 8/26

2nd call 8/26

6:30P

6 pm

368-5620	3				8/26/97
632-0959	1	2			
467-4328	8 BUSINESS				
993-7146	8 PAGER				
328-5342	3				
433-2882	2				
544-3338	2				
441-9083	8 BZ				
763-9815	2				
621-1432	3				
232-6917	1	1	1		
283-1841	2				
410-5337	8 D/C				
782-5890	1	1	1		
521-7805	8 PAGER				8/27/97
216-6194	8 BUSINESS (machine)				
515-6262	8 modem/fax				
625-6189	8 Business (Machines)				
389-5771	2				
216-3958	8 Business (machine)				
389-4374	8 Business (machine)				
365-4610	3				
782-0524	2				
994-9070	8 PAGER				
608-0740	8 PAGER				
632-2982	8 D/C				
935-2973	1	2			
246-9506	2				
441-9396	1	2			
232-2219	1	3			
726-9853	8 D/C				
991-8662	8 PAGER				
932-6906	1	1	1		
464-9529	8 Business				
994-9769	8 PAGER				
860-4516	8 BZ				
323-0844	8 D/C				
382-7816	8 BZ (FAST)				
441-0974	8 modem/fax				
506-5983	8 Business				
772-3886	8 D/C				
441-4934	8 BZ				
224-7590	8 Business				
955-2053	8 PAGER				
243-7276	8 D/C				
654-0311	3				8/27

1/2 hr

1 1/2 hrs

730p

1 pm

223-0347	8 BZ			8/27/97
524-2440	3			
442-7468	8 Business (no VM option)			
283-9659	8 D/C			
938-9179	1	2		
760-6047	8 D/C			
767-0855	1	1	1	
547-3928	3			
244-6124	2			
706-1217	2			
440-0385	2			
575-9508	2			
328-8417	1	1	1	
215-2917	8 Business (HOSP)			
996-7898	8 PAGER			
433-3090	8 D/C			
625-9430	2			
344-0987	3 too young			
324-6413	2			
624-0864	8 Business NO			
329-3383	2			
725-3679	8 D/C			
515-0466	8 D/C			
322-1482	3			
344-8088	8 D/C			
575-2187	8 Business (Nextel)			
938-4669	2			
760-8135	8 D/C			
764-9772	8 D/C			
344-7059	2			
442-9247	8 BZ			
516-5018	8 BZ (FAST)			
439-7561	8 Business NO			
389-5553	2			
996-0697	8 PAGER			
217-6873	8 BUSINESS NO			
443-5166	2			
506-7680	1	3		
547-9461	8 D/C			
230-0598	8 D/C			
784-7908	3			
244-8197	8 D/C			
721-5018	8 Business NO			

Appendix 2.

Community Consultation: Random Digit Dialing

C. 35 interview sheets

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 433-1753

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/17/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 1

   Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 1

   Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 1

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 286-8052

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/12/97

Agree to interview (1 = no; 2 = yes) 1

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 1

Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 1

Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 1

Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 236-2172

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/18/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 1

Comments (use continuation sheet as needed):
Some people have allergic reactions
+ you have no idea what other RX's they may be on.

2. Would respondent want to participate (1 = no; 2 = yes) + could have interactions 1

Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) unsure

Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 722-6559

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/19/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 1

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 1

Comments (use continuation sheet as needed):

"I'm over 80 yrs old + I'm against giving anyone placebo's. They should be given the same help"

2. Would respondent want to participate (1 = no; 2 = yes) 1

Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 1

Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 623-6661

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/20/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

Unsure - would need more info

2. Would respondent want to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

same as above

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

same as above

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

NO - not interested in more info

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 243-2912

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/21/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 1

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 1

   Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 1

   Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 1

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 232-6917

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/26/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 1

   Comments (use continuation sheet as needed):
   I believe people should decide on their own tx & also be sure that all these drugs are harmless

2. Would respondent want to participate (1 = no; 2 = yes) 1

   Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 1

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 762-8054

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/18/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 1

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 1

   Comments (use continuation sheet as needed):
   It'd be a shame to get the placebo - Especially if the RX works!

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 723-6642

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/19/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 1

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) "No need - I had pacemaker"

Comments (use continuation sheet as needed):

"Already had 2 heart attacks & I have a pacemaker now - I'm over 80 yrs old"

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 282-4795

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/17/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 783-7353

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/17/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 362-4554

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/17/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

   Anything that could help would be nice

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 525-8261

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/12/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 1

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed): The older one gets the more we touch your become with your health issues - Good luck with this study

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 522-2322

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/18/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 364-1478

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/18/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):
"There has to be some way to test these things & this sounds as good as any"

2. Would respondent want to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):
"Good luck"

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 364-5211

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/18/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):
   Would really like to be sure to get RX + not placebo ☺

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 243-7236

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/18/97

Agree to interview (1 = no; 2 = yes) 1

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):
We have tried it without the drugs for already too long - lets give EVERYONE the RX - + no placebo

2. Would respondent want to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):
Only if she was sure to have the RX & not placebo -

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):
Same as above

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 324-2429

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08,18,97

Agree to interview (1 = no; 2 = yes) 1

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

   Good luck - It sounds like a good thing

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 522-6530

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/19/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

Biggest concern would be "what if the family/person would sue"

2. Would respondent want to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

"good luck"

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 782-3214

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/20/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

   I'd need more information - I would support it in a hospital setting. -

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

   But if it's severe enough to do risk/benefit why not try?

   Same as above

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

   Same as above

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 2466428

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/20/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 1

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 789-9440

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08,21,97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 1

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

"If the risk associated w/ these 2 drugs are minimal - then DEFINATELY support it" 2

2. Would respondent want to participate (1 = no; 2 = yes)

Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 723-6203

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/21/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 937-2178

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/25/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 1

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

"If the paramedics felt they'd give this tx to their own family - then YES - by all means" 2

2. Would respondent want to participate (1 = no; 2 = yes)

Comments (use continuation sheet as needed):

Same

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

Same

4. General Comments (use continuation sheet as needed):

"They need to do what's best for all concerned"

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 232-8380

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/25/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

OK - as long as they also get the Standard tx -

2. Would respondent want to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

same as above

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 782-5890

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) _

Date (month / day / year) 08/26/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 1

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):
   But Im not planning to have a cardiac arrest -

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 523-6833

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/26/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

"I'd want the real drug"

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 784-8896

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/26/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 1

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 764-1898

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/26/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 1

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 325-3059

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/27/92

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 1

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

If it can help – then YES

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 524-9505

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/27/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 1

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

"I hope you're not just presenting a biased view—" <I explained about the testing on animals then>

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 782-1989

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/27/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 1

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

I'm all for research - but just make sure that Dr. Longstreth is not Dr. Frankenstein

2. Would respondent want to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 328-8417

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/27/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 2

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 767 0855

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/27/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 1

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

"Keep up the good work"

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

CONTACT SHEET FOR B-CPR STUDY

Telephone Number 932-6906

Result of call (1 = contacted person; 2 = no answer; 3 = answering machine; 8 = other, specify) 1

Date (month / day / year) 08/27/97

Agree to interview (1 = no; 2 = yes) 2

Guess gender of respondent (1 = man; 2 = woman; 3 = uncertain) 1

Respondent 40 years or older (1 = no; 2 = yes) 2

1. Support the study (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

2. Would respondent want to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

3. Would respondent want family member to participate (1 = no; 2 = yes) 2

   Comments (use continuation sheet as needed):

4. General Comments (use continuation sheet as needed):

Wants to talk to investigator (1 = no; 2 = yes) 1

Suggested time and date for call-back:

Whom to ask for:

Appendix 3.

Summary of opinions of survivors of out-of-hospital cardiac arrest

MEMO

Date: August 18, 1997

To: SCD/EMS Research/CQI Committee
Will Longstreth, M.D.
Peter Kudenchuk, M.D.

From: Carol Fahrenbruch

Re: VF Survivor Community Consultation

The VF survivor community consultation was held on Saturday, August 16th, 1997. There were six attendees among the eight who said they would come:

Names of these individuals covered for reasons of confidentiality

At the end of the session, all six reponded in the affirmative to each of the questions. A copy of the survey form is attached. Five individuals added comments. Their remarks are transcribed below:

"There is no excuse not to do what is best to save the brain of everyone you can. Do not hesitate to do it."

"Full agreement with the study but would prefer some more discussion of the risks (or absence of) involved."

"Nothing ventured nothing gained."

"Biggest worry after a cardiac arrest is if person has been without oxygen too long - this study will help bring out a medicine to improve this."

"Anything to help improve your life after a heart problem."

Another attendee made the personal comment to me to that, "You (Medic One) should just conduct whatever research you think best and then lie about it (to the FDA/Human Subjects regarding the community consultation process)."

My summary of the themes that emerged during the discussion is on the next page. Please add to the list or help me express these ideas better if you heard other thoughts, or have suggestions about framing these.

1. "Why us?" The question was asked in a couple of ways:

   a. What expertise do we have as cardiac arrest survivors that could make us any more suitable to comment than any other group?

   b. How could any lay group evaluate this issue?

   and then a twist on this theme:

   c. Wouldn't our views be somewhat discounted? We would be expected to be supportive.

2. "What precedent is there to guide our decision?"

   For example, one participant asked about how the waiver of informed consent was handled for patients treated in the emergency room.

3. Risks/benefits associated with the study medications

   Participants focused on this despite the assurances of the presenters that these drugs were very safe and that approval for their use in this setting belonged in the domain of Human Subjects and the FDA.

4. The "placebo problem"

   If the two study agents hold such promise, isn't it unethical to randomize some patients to a placebo? Why not give every eligible patient the drugs and then use historical controls? The group kept repeating that we already had the baseline data for this approach.

   There was a surprising amount of discussion related to methodology. Similar to the discussion regarding risks and benefits, participants wanted to dig into this instead of being reassured that it was not the purpose of the community consultation. Dr. Longstreth let participants know that the study design was guided by FDA/Human Subjects guidelines for clinical trials. Tom Walsh drew a figure to illustrate potential problems with using baseline data as the control group.

5. Unawareness that cardiac and neurological recovery are two different processes.

   The question was posed whether it was really true that some patients recovered from the cardiac arrest but with a bad or comatose neurologic outcome. This was asked several times in several ways. It appeared to be a sobering new concept to this group. One survivor asked why he had not previously heard of poor neurologic outcomes after cardiac arrest.

   I wished that I had prepared for this question with some data regarding neurologic status at the time of hospital discharge, and then subsequent recovery/not.

6. Unethical not to proceed with research that has the potential to improve outcome.

   This was the final consensus, with comments such as "Do it and don't tell us." "We won't know and we don't care." "Keep trying to make resuscitations better."

7. Personal stories. Several participants related personal accounts of their cardiac arrest(s) and subsequent recovery.

Community Consultation
Wedgwood Fire Station
August 16, 1997

Please circle your replies to the following questions:

1. Would you support such a study being done in your community, specifically, a study in which patients and their families do not have a chance to give their consent to be in the study?

   (yes) no

2. If you had a cardiac arrest and were treated by Seattle paramedics, would you want to be enrolled into this type of study?

   (yes) no

3. If a family member of yours had a cardiac arrest and were treated by Seattle paramedics, would you want him or her to be enrolled into this type of study?

   (yes) no

4. Comments (continue on the back, if you like)

   There is no excuse not to do what is best to save the brain of everyone you can. Do not hesitate to do it.

5. (optional) Please circle your:

age:	< 40	40-65	(66+)
gender:	(F)	M	
status:	(cardiac arrest survivor)	family member	

Thank you for your participation today.

Community Consultation
Wedgwood Fire Station
August 16, 1997

Please circle your replies to the following questions:

1. Would you support such a study being done in your community, specifically, a study in which patients and their families do not have a chance to give their consent to be in the study?

   yes ✓ no

2. If you had a cardiac arrest and were treated by Seattle paramedics, would you want to be enrolled into this type of study?

   yes ✓ no

3. If a family member of yours had a cardiac arrest and were treated by Seattle paramedics, would you want him or her to be enrolled into this type of study?

   yes ✓ no

4. Comments (continue on the back, if you like)

5. (optional) Please circle your:

age:	< 40	40-65	66+	82
gender:	F ✓	M		
status:	cardiac arrest survivor X 2	family member		

Thank you for your participation today.

Community Consultation
Wedgwood Fire Station
August 16, 1997

Please circle your replies to the following questions:

1. Would you support such a study being done in your community, specifically, a study in which patients and their families do not have a chance to give their consent to be in the study?

   (yes) no

2. If you had a cardiac arrest and were treated by Seattle paramedics, would you want to be enrolled into this type of study?

   (yes) no

3. If a family member of yours had a cardiac arrest and were treated by Seattle paramedics, would you want him or her to be enrolled into this type of study?

   (yes) no

4. Comments (continue on the back, if you like)

"Full agreement with the study, but would prefer some more discussion of the risks (or absence of) involved" of

full agreement with study
but would like - some more discussion
of risks & absence of involved

5. (optional) Please circle your:

age:	< 40	40-65	(66+)
gender:	F	(M)	
status:	(cardiac arrest survivor)	family member	

Thank you for your participation today.

Community Consultation
Wedgwood Fire Station
August 16, 1997

Please circle your replies to the following questions:

1. Would you support such a study being done in your community, specifically, a study in which patients and their families do not have a chance to give their consent to be in the study?

yes no

2. If you had a cardiac arrest and were treated by Seattle paramedics, would you want to be enrolled into this type of study?

yes no

3. If a family member of yours had a cardiac arrest and were treated by Seattle paramedics, would you want him or her to be enrolled into this type of study?

yes no

4. Comments (continue on the back, if you like)

NOTHING VENTURED NOTHING GAINED

5. (optional) Please circle your:

age:	< 40	40-65	66+
gender:	F	M	
status:	cardiac arrest survivor	family member	

Thank you for your participation today.

Community Consultation
Wedgwood Fire Station
August 16, 1997

Please circle your replies to the following questions:

1. Would you support such a study being done in your community, specifically, a study in which patients and their families do not have a chance to give their consent to be in the study?

   (yes) no

2. If you had a cardiac arrest and were treated by Seattle paramedics, would you want to be enrolled into this type of study?

   (yes) no

3. If a family member of yours had a cardiac arrest and were treated by Seattle paramedics, would you want him or her to be enrolled into this type of study?

   (yes) no

4. Comments (continue on the back, if you like)

   Biggest worry after a cardiac arrest is if person has been without oxygen too long - this study will help bring out a medicine to improve this

5. (optional) Please circle your:

age:	< 40	40-65	(66+)
gender:	(F)	M	
status:	cardiac arrest survivor	(family member)	

Thank you for your participation today.

Community Consultation
Wedgwood Fire Station
August 16, 1997

Please circle your replies to the following questions:

1. Would you support such a study being done in your community, specifically, a study in which patients and their families do not have a chance to give their consent to be in the study?

(yes) no

2. If you had a cardiac arrest and were treated by Seattle paramedics, would you want to be enrolled into this type of study?

(yes) no

3. If a family member of yours had a cardiac arrest and were treated by Seattle paramedics, would you want him or her to be enrolled into this type of study?

(yes) no

4. Comments (continue on the back, if you like)

ANY THING TO HELP IMPROVE YOUR LIFE AFTER HEART PROBLEM

5. (optional) Please circle your:

age:	< 40	40-65	(66+)
gender:	F	(M)	
status:	(cardiac arrest survivor)	family member	

Thank you for your participation today.

MEMO

Date: August 19, 1997

To: SCD/EMS Research/CQI Committee
Will Longstreth, M.D.
Peter Kudenchuk, M.D.

From: Carol Fahrenbruch Carol

Re: VF Survivor Telephone Survey for BCPR Study

Maryann surveyed by telephone seven VF survivors who were unable to attend the community consultation meeting on August 16th.

All seven were supportive of the study being done in the community.

Six would want to be enrolled in the study. One did not want to consider a recurrent cardiac arrest and replied that he would not want to be enrolled.

All seven would want a family member to be enrolled.

Two comments were noted:

"Sounds like an excellent idea. Heartily agree."

"Sounds like really good idea. I was lucky; my husband did CPR!"

Appendix 4.

Public Service Announcement

	Last	Chg		Div	PE	Vol	Last	Chg
			Trimas s	.28	16	98	28¾	+¼
			Trinty s y	.48	21	2144	44⅝	-⅝
			TritEng	...	...	1450	38⅛	-⅛
			TrtzHhn h	.25	43	1247	24⅝	-⅛
			TRWs	1.34	15	2968	57¼	-⅛
			Tubscp	...	28	600	30¾	+⅛
			TucsEP	...	6	820	16⅛	-⅛
			Tuperwrd	.88	11	2878	24¼	-1
			TVAztc n	...	25	1364	18	-⅛
			20Cnln	.20	24	440	34⅝	-⅛
			TXICp	.30	12	1872	44¼	+1⅛
			TycoIntl s e	.02	19	20664	38	-⅛
			TysonFd	.10	28	2220	19⅝	+⅛
						U		
			UAL	...	10	6851	86⅛	-2⅛
			Ucarint	...	12	5530	37⅛	-1⅛
			UGI	1.44	18	247	26⅝	-⅛
			UltrDiaSh e	1.10	...	4809	30½	-½
			Unicorn	1.60	11	23891	27⅝	+⅛
			Unifrh	.56	20	1298	38⅛	-⅝
			UniNVs e	.82	10	9652	52¼	-⅛
			Unilevr s e	.65	9	479	30	-⅛
			UnCmp	1.80	90	5548	54⅛	-⅝
			UCarb h	.90	10	7120	46½	-⅝
			UnlEl	2.54	13	3565	37¼	-⅛
			UnPac	1.72	19	11903	62⅛	-1⅛
			UnPacRs	.20	17	10058	24⅛	-⅛
			UnlnP	1.60	21	1108	59	-1⅛
			UnTex	.20	11	2029	22½	...
			Unisrc n	.80	19	6181	16⅜	-⅛
			Unsys	...	42	23326	13	-⅛
			Unsys prA	3.75	...	355	43¾	-⅛
			UAM h	.80	16	1215	26⅛	-⅛
			UDomI	.28	8	549	25⅛	-⅛
			UnDomR	1.01	22	1224	14	...
			UHltCrs	.03	23	10566	46⅛	-⅝
			UnHdMrd	...	69	1701	33⅛	+⅛
			USFlit	...	45	7005	39⅛	-⅛
			UnTechs	1.10	17	26522	69⅝	-2⅛
			UnvlCp	1.06	11	754	37⅛	-⅝
			UnvFdxh	1.06	21	1787	38⅛	-⅝
			UnvHlt	...	23	1431	43¾	-⅛
			UnvsnCam	...	52	291	62⅜	-½
			Unocal	.80	...	11045	39⅝	...
			Unova wi	...	35	1822	18⅜	-⅛
			UNUMs	.57	20	5445	47½	-½
			UNUM Mids	2.20	...	13	26⅛	-⅛
			USAir		7	10482	45⅞	-⅛
			US Bnc e	1.81	30	4438	99½	-1½
			USInd s p	.20	10	586	26⅜	-⅛
			USSrg	.16	18	6015	26⅜	-½
			USWstC	2.14	15	8619	39½	-⅛
			JSWstMG	...	...	15111	25¼	-⅜
			USAWst	...	46	12214	37⅛	+⅛
			USF&G	.28	9	4561	19¼	-⅛
			USG	...	25	1668	45⅛	-⅛
			UST	1.62	13	3262	30⅜	-½
			USXMar	.76	17	7575	34⅞	+⅛
			USXStl	1.00	7	4919	33⅛	+½
			Utilic	1.76	14	1273	31⅛	+⅛
						V		
			ValRes n	...	32	74	27¼	...
			Valassis	...	18	966	28¼	-⅛
			Valero	.32	25	1391	29⅝	-⅛
			Valhl	.20	16	142	9⅛	-⅛
			ValNtBnY	1.10	17	183	31⅞	-⅛
			Valspr s	.36	21	322	29½	-⅛
			Varco	...	30	4593	62⅛	+⅜
			Varlan s	.36	16	1271	58	-1⅛
			VastrRes	.30	16	248	40⅝	-½
			VebAkt n	...	...	22	55⅛	+⅛
			Vencor	...	30	10767	27	-1⅛
			VeritasDGC	...	31	712	40⅛	...
			Vesta	.15	20	335	56⅛	-⅛
			VFCp h	1.44	17	1575	88⅝	-⅛
			Viad	.32	44	726	18⅛	+⅛
			VinPt s h	.08	19	1287	22⅛	+⅛
			Vishay	...	24	1661	22⅛	-½
			Vitro e	.12	...	4628	11⅞	-½
			Vodafne e	.41	28	886	55	-⅜
			VoltInf	...	31	423	66⅛	+1⅛
			Vornad s	1.28	45	1628	43⅛	-⅜
			VulcM	1.88	14	419	86½	-1⅛
						W		
			Wachvia h	1.76	18	3005	73⅝	-1⅛
			WalMart	.27	25	41530	34⅛	...
			Walgm s h	.25	32	8907	28	+½
			WalCS h	.62	20	109	37⅛	-⅛
			Warnac	.32	23	1670	28⅛	-⅛
			WarnL	1.52	47	12590	138⅛	-4⅛
			WaGas	1.18	14	328	25⅛	-⅛
			WaPost	4.80	18	1266429	¼	-3¼
			WshMgmt e	.66	...	358426	23	-6
			WastMin	...	...	3634	6¼	-1⅛
			Waters	...	...	341	42⅝	-⅛
			WatsonP s	...	34	2792	31⅛	+⅛
			WBKStry e	.34	...	2189	30⅝	+⅛
			WthfrdE	...	26	2317	49⅝	+⅛
			WeinRl	2.56	19	242	39⅛	-⅛
			WelsMk	.96	19	93	34½	+⅛
			WelpitHl	...	17	3543	47⅞	-5⅛
			WellsF	5.20	28	2433	288¼	-7¼
			Wendy	.24	16	5590	20⅛	-⅛
			WsticEg	1.24	15	389	20⅛	-⅛
			WestAlsn	...	...	5312	85⅛	-⅛

Calif. court upholds layoffs based on age

LOS ANGELES TIMES

SAN FRANCISCO — A divided California Supreme Court decided yesterday to let stand a lower court ruling that allows companies to lay off older workers and keep younger employees to save money.

The court's action means that trial courts throughout the state will be bound by the July ruling in favor of employers. A Court of Appeal in the case ruled that firing predominantly older workers is not age discrimination if the motivation is economic.

"It is pretty devastating for anyone age 40 or older for this to remain law," said William Quackenbush, a labor and appellate lawyer. "Employers are now going to be free to arrange their restructuring and business decisions around this case."

Sarah Rios, a human-resources consultant for t Employers Group, an organization of 5,000 state bu nesses, said employers will now have more flexibili

"It will have a positive impact on California emplo ers," she said. "Employers are really scared of ter nating employees nowadays because they can be su in so many directions."

The court's action stemmed from a lawsuit broug by Michael Marks, a former aerospace accountant w lost his job with Loral in 1992.

Marks said he was discriminated against on the bas of age. Loral officials said Marks was laid off in a co cutting move because he made more money and h more benefits than younger workers.

Appendix 5.

Text of letter sent to Seattle cardiologists, emergency room directors and nursing directors of intensive care units

«DATA List Providers»
«SET date=?date of letter»

«date»

«address»

Re: Clinical Trial of Brain Cardiopulmonary Resuscitation in Seattle

Dear Dr. «IF title = "Ms"»Ms.«ELSE»«IF title = "Mr"»Mr.«ELSE»Dr.«ENDIF»«ENDIF» «name»:

Most patients whom Seattle paramedics resuscitate from cardiac arrest never awaken, despite the excellence of the care they receive. In other words, these patients never regain enough neurologic function to allow them to follow commands or to have comprehensible speech. Effective treatments to protect the brain from the global brain ischemia that accompanies cardiac arrest, brain resuscitation, would allow more patients to awaken after cardiac arrest. Such treatments are currently not available. Based on experiments in animals and experience in humans, two widely available agents hold promise in brain resuscitation. Magnesium can block the deleterious effects of excessive excitatory neurotransmitters, and diazepam can enhance the counterbalancing effects of inhibitory neurotransmitters.

My co-investigators and I aim to test the hypothesis that one of these agents or their combination will increase the proportion of patients awakening after cardiac arrest. We will use a randomized, double-blind, placebo-controlled clinical trial with a factorial design. Patients whom paramedics resuscitate from cardiac arrest will be eligible for the study assuming that they are 18 years or older, have not already achieved the primary outcome of awakening, and have endotracheal intubation. As soon as possible after return of pulse or blood pressure, paramedics will inject, each over two minutes, the two syringes containing study medications. The first syringe will have either 4 ml with 2 gm of magnesium sulfate or 4 ml of normal saline. It will be followed by the second syringe, which will have either 2 ml with 10 mg of diazepam or 2 ml of normal saline. The contents of each syringe, active agent or placebo, will be unknown to the paramedics. The study involves no other interventions.

Informed consent can not be obtained prior to the injections of study medications because eligible patients will be unconscious, because of the need to intervene as soon as possible upon reperfusion, and because of the anticipated safety of these agents. We have secured approval from the Human Subjects Review Committee at the University of Washington and the Food and Drug Administration to use an emergency waiver of consent. Paramedics will leave an information sheet with every patient who is enrolled in the study. We ask that the patient's attending physician review this information with the patient's family and, if appropriate, the patient. A copy of the information sheet is included for your review.

Details on all of the outcomes for the study are currently collected by Medic One personnel as part of the program's ongoing efforts to assure the highest quality care possible. The primary outcome will be awakening, and the primary analyses will involve comparisons of the proportion of patients awakening between those receiving an active agent and those receiving the identical appearing placebo. We encourage everyone caring for these patients to be as precise as possible in charting the time of awakening. Approximately 300 patients will be enrolled and randomized over two years yielding a power of 90% to detect a decrease in the percent who never awaken from 60% to 40%.

If one of these agents or their combination proved effective, the study would have immediate implications about how cardiopulmonary resuscitation is performed, not only outside but inside the hospital, not only in Seattle but elsewhere. Even should the study fail to show any benefit, it would still be an important first step. Future studies could proceed to examine different doses or different agents in larger numbers of patients, striving to make the concept of brain resuscitation a reality.

If you have any questions about the emergency waiver of consent, the request that the patient's attending physician review information about the study with the patient's family, the request that everyone caring for these patients be as precise as possible in charting the time of awakening, or anything else about this study, please contact me as indicated below.

Sincerely,

W. T. Longstreth, Jr, MD
Department of Neurology
Box 359775
Harborview Medical center
325 Ninth Avenue
Seattle, WA 98104-2499
223-3251

voice: 206 731-3251
facsimile: 206 731-8787
e-mail: wl@u.washington.edu

INFORMATION SHEET ABOUT THE BRAIN-CARDIOPULMONARY RESUSCITATION (B-CPR) TRIAL

A relative or close friend of yours recently experienced a cardiac arrest. Medic One paramedics have resuscitated and enrolled this patient in the Brain-Cardiopulmonary Resuscitation (B-CPR) Trial. Federal regulations usually do not allow patients to be enrolled in a study without their informed consent or without the consent of their next-of-kin. However, in certain limited situations, such as emergency medicine research, the U.S. Food and Drug Administration (FDA) does allow some studies to be conducted without consent. You should know that this particular study has been reviewed by the FDA, the University of Washington, and the Seattle Fire Department. All have agreed that a waiver of consent for this study is permissible and does not pose additional risks to patients involved. In fact, they may benefit from the treatment.

To explain further, during a cardiac arrest, the blood stops flowing to the brain and damage may occur. People who are revived or resuscitated from a cardiac arrest may never regain consciousness. Although the heart has been resuscitated, the brain has not. The purpose of this study, called a clinical trial, is to test whether or not one of two promising medications or their combination will increase a person's chances of regaining consciousness after being resuscitated from a cardiac arrest.

To be effective, these medications need to be given as soon as possible after the heart starts pumping blood again. Consequently in this study, Seattle paramedics inject the study medications in patients whom they have resuscitated from a cardiac arrest if the person is 18 years or older and has not immediately regained consciousness. The two injections are each given over two minutes into an intravenous line, which is routinely placed in all patients whom paramedics treat for cardiac arrest. The first injection contains 4 cc (less than a teaspoonful) of magnesium sulfate or an identical appearing placebo. The second injection contains 2 cc (less than half a teaspoonful) of diazepam or an identical appearing placebo. Other than these two injections, paramedics treat these patients in the same way as they would treat anyone with cardiac arrest. Because all subjects who are enrolled in this study must be unconscious, they should not experience any discomfort as a consequence of these two injections. Even in patients who are awake, such injections produce little, if any, discomfort.

One of the people involved in this study will be contacting you in the near future to discuss the study in greater detail. If you would like to talk to someone as soon as possible, please call 521-1210. Alternatively, you can contact Dr. Will Longstreth or Dr. Mike Copass through the Harborview Medical Center paging operator at 731-3000.

Appendix 6.

Letter from Food and Drug Administration date 1997 October 17

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

IND 52,523

OCT 17 1997

W.T. Longstreth, Jr., M.D.
Department of Neurology
Box 359775
Harborview Medical Center
325 Ninth Avenue
Seattle, Washington 98104-2499

Dear Dr. Longstreth:

Reference is made to your Investigational New Drug Application (IND) submitted pursuant to section 505(i) of the Federal Food, Drug, and Cosmetic Act for diazepam injection (10 mg) and magnesium sulfate injection (2 mg) and to your amendment dated August 26, 1997.

We note that your August 26, 1997 amendment responds to deficiencies in procedures/ information required for use of exception from informed consent in emergency research as required under 21 CFR 50.24, which precluded the Agency from granting permission for you to conduct your proposed clinical investigation. These deficiencies were communicated to you in an Agency letter dated August 4, 1997.

We have completed our review of your amendment and, as communicated to you by Mr. Merril Mille of this Division on October 3, 1997, have concluded that you may proceed with your proposed clinical investigation. With the incorporation of the changes outlined in the August 26, 1997 submission into the protocol, we agree that your procedures/information are acceptable for use of exception from informed consent in emergency research under 21 CFR 50.24.

You are responsible for compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations (Title 21 of the Code of Federal Regulations). These responsibilities include:

1. **Obligations Associated With 21 CFR 50.24**
   We remind you that 21 CFR 312.54 states that: 1) when a sponsor receives from the Institutional Review Board (IRB) information concerning public disclosures required by 21 CFR 50.24(a)(7)(ii) and (a)(7)(iii), the sponsor shall promptly submit to the IND file and to Docket Number 95S-0158 in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, copies of the information that was disclosed, identified by the IND number; and 2) the sponsor shall monitor such investigations to identify when an IRB determines that it cannot approve the research because it does not meet the criteria in the exception in §50.24(a) or because of other relevant ethical concerns,

and promptly shall provide this information in writing to FDA, investigators who are asked to participate in this or a substantially equivalent clinical investigation, and other IRB's that are asked to review this or a substantially equivalent investigation.

2. **Future Protocols**
Please note that the IND regulations require submission of a separate IND for each protocol utilizing exception from informed consent in emergency research (21 CFR 50.24). For this reason and for administrative reasons, we request the submission of a new IND application for any new protocol regardless of the informed consent procedures.

3. **Safety Reporting Requirements**
You are responsible for reporting any unexpected fatal or life-threatening experience to FDA by telephone no later than three working days after receipt of the information (21 CFR 312.32) and submission of annual progress reports.

Please forward all future communications concerning this IND in triplicate, identified by the above IND number, and addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research, HFD-120
Attention: Document Control Room
5600 Fishers Lane
Rockville, Maryland 20857

Should any questions arise concerning this IND, please contact Mr. Merril Mille, Senior Regulatory Management Officer, at (301) 594-5528.

Sincerely yours,

Paul Leber, M.D.
Director
Division of Neuropharmacological
Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ROUTING AND TRANSMITTAL SLIP

Date: 1/5/98

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. [redacted]		
2. [redacted]		
3. [redacted]		
4.		
5.		

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

REMARKS

Please submit the attached Document to Docket Number 955-0158 in accordance w 21 CFR 50.24

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
Merrill Mabb (MILLEM) 4-5528	WOC 2/4033
	Phone No.

5041-103
*U.S. Government Printing Office: 1995 — 387-722/20018

OPTIONAL FORM 41 (Rev. 1-94)
Prescribed by GSA